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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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SAMUEL L FOX
STERNE KESSLER GOLDSTEIN & FOX
1100 NEW YORK AVENUE NW STE 600
WASHINGTON DC 20005-3934

EXAMINER

CUNNINGHAM, T

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

08/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/474,388

Applicant(s)
Springer et al.

Examiner
Thomas Cunningham

Group Art Unit
1644



☒ Responsive to communication(s) filed on May 24, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 71-73, 75-78, and 80-82 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 71-73, 75-78, and 80-82 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1644

1. Claims 71-73, 75-78, and 80-82 are active.

2. Amended claim 74 has not been entered. It is objected to because claim 74 has been previously canceled.

3. (Moot) The prior rejection of claim 79 under 35 U.S.C. 112, fourth paragraph as failing to further limit the claimed subject matter of independent claim 71 is moot. The ICAM-1 products of claim 71 would inherently have the same amino acid sequence as that of Fig. 8 as claimed in claim 79. Therefore, claim 79 does not further limit the subject matter of claim 71.

--Claim 79 has been canceled without prejudice, see Examiner's comments below in response to rejection under 35 U.S.C. 112, first paragraph. The prior rejection is moot.

4. (Moot) The prior rejection of claim 73 under 35 U.S.C. 112, fourth paragraph as failing to further limit the claimed subject matter of independent claim 72 is moot. The term "specifically bind" does not further limit the term used in claim 72 "bind".

--The Examiner has made the claim numbering changes requested by the Applicant. It is clear from the context that "claim 73" filed 10/15/99 should properly be numbered "claim 72". This has been done and dated and initialed by the Examiner. Claim 73 as pending in the amendment of 1/7/97 is still active.

4. Claim 71 is rejected under 35 U.S.C. 112, first paragraph as failing to describe so as to enable ICAM-1 having amino acid sequences other than the sequence of Fig. 8. There are no descriptions of allelic variants, or mammalian homologs of ICAM-1 sequences, and it would have been unpredictable whether such variants exist. Thus, one with skill in the art would not have had a reasonable expectation of being able to make and use

Art Unit: 1644

variants of ICAM-1 other than those having the sequence of Fig. 8.

--Applicant's comments on pages 3-4 of the last response (Paper No. 16, Amendment E) have been considered and are persuasive for claims limited to the ICAM-1 sequence of Fig. 8 or for a claim to a probable genus of minor allelic variants of ICAM-1 including the ICAM-1 sequence of Fig. 8. One with skill in the art would reasonably expect some minor allelic variants of the ICAM-1 sequence, e.g. due to somatic mutation. However, the instant specification does not explicitly describe by complete amino acid sequence any other allelic variant of the sequence of Fig. 8 and a subsequent claim to a specific allelic variant with an amino acid sequence different than that of Fig. 8 may be separately patentable, See In re Deuel, 34 USPQ2d 1210 (Fed. Cir. 1995).

5. (Withdrawn) The prior rejection of claims 71-73, 74-78 and 80-83 under 35 U.S.C. 112, first paragraph to the extent that they embrace ICAM-1 products that do not have the sequence of Fig. 8 is withdrawn for minor allelic variants of ICAM-1 that would not be expected to have significantly different functional properties.

6. (Necessitated by amendment) Claims 80-82 are rejected under 35 U.S.C. 112, first paragraph as lacking adequate description in the specification as filed for an "artificial membrane comprising purified or isolated ICAM-1" that is capable of binding to LFA-1, Mac-1 or p150,95.

Art Unit: 1644

7. Claims 71-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomassini, thesis 8624033 (1986) or Tomassini et al., J. Virol. 58:290-295 (1986).

These claims are directed to purified or isolated ICAM-1 preparations capable of binding to LFA-1, Mac-1 or p150,95. Page 58 of the cited document teach 400-fold immunoaffinity purified 90 kDa HRRP (ICAM-1). The cited document is silent as to whether the 90 kDa HRRP product (ICAM-1) binds to a member of the LFA-1 family, but would inherently have this property as it would comprise the same binding site residues as the ICAM-1 products encompassed by the instant claim language.

--The Applicant's arguments on pages 5-6 of the response have been considered, but are not persuasive. The Applicant urges that the prior art HRRP preparation was not conclusively demonstrated to bind to radio labeled human rhinovirus because of poor virus binding. Since the HRV and LFA-1 binding sites on the ICAM-1 (HRRP) molecule overlap it is urged that one would not expect that the HRRP preparation of Tomassini would in fact bind to LFA-1. This argument is a good argument however it is not persuasive because poor binding of radio labeled HRV is more likely to be attributable to chemical denaturation and subsequent disruption of the binding sites on the virus (not HRRP or ICAM-1) by radio labeling protocols. The HRRP (ICAM-1) product of the

Art Unit: 1644

cited prior art would inherently retain its native characteristics. Applicant's argument would be plausible if the HRRP (ICAM-1) of the prior art had been radio labeled.

8. Claims 71-73 and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomassini, thesis 8624033 (1986) or Tomassini et al., J. Virol. 58:290-295 (1986). These claims encompass forms of ICAM-1 produced in different human tissues or by different human cell lines, viz. claim 75 (spleen), claim 76 (JY cells), claims 77 (myelomonocytic cell line), and claim 78 (fibroblast).

The two cited references teach HRRP (ICAM-1) produced by HeLa cells. They do not teach HRRP (ICAM-1) produced in other cells.

Tomassini et al., page 295, first column, last paragraph indicates that the HRV receptor is ubiquitous in the human body, and thus one with ordinary skill in the art at the time of invention would have had a reasonable expectation of isolating HRRP (ICAM-1) from any tissue in the human body using the methods taught by the cited references for the purpose of studying of modulating the attachment of HRV to human tissues.

--Applicant urges that Tomassini may not have had HRRP (ICAM-1) in its active form. This argument has been considered above and

Art Unit: 1644

is not persuasive because the prior art HRRP was not radio labeled.

9. Claims 80-82 as amended are rejected under 35 U.S.C. 102(b) as being Tomassini, thesis 8624033 (1986) or Tomassini et al., J. Virol. 58:290-295 (1986). These claims are now limited to ICAM-1 within an "artificial lipid membrane". The remaining issue is whether HRRP or ICAM-1 when associated with detergents, such as in micellar form, would be considered an artificial lipid membrane. ICAM-1 detergent micelles present within a microtiter plate or other container could be considered an artificial planar membrane. Applicant should elaborate on their definition of artificial lipid membrane. If this excludes ICAM-1 associated with detergents, then this rejection will be withdrawn.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas M. Cunningham, Ph.D, J.D. whose telephone number is (703) 308-3968. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TC
THOMAS M. CUNNINGHAM
PRIMARY EXAMINER
GROUP 1800